Policy Title:	Uses and Disclosures for Research Purposes
Policy Number:	AS-006
Effective Date:	July 1, 2013
Approval:	Thomas O. Forslund, Director — Date: 6/17/13

Purpose:
This policy describes the requirements for Wyoming Department of Health (WDH) to use or disclose protected health information (PHI) for research purposes.

Scope:
This policy applies to all WDH workforce.

Definitions:
Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Policy:

1. **General**
   a. WDH is permitted to use or disclose PHI for research purposes consistent with the provisions of federal and state law. It is not required to do so, unless otherwise required by law.
   b. De-identified health information is not considered PHI, and is, therefore, not subject to the provisions of the Privacy Rule. WDH encourages the use of de-identified health information in lieu of PHI. The methods for de-identifying PHI are articulated in WDH Policy AS-007; De-Identification and Re-Identification of Protected Health Information; Limited Data Sets and Data Use Agreements.

2. **Uses or disclosures pursuant to a valid authorization.** An individual may authorize WDH to use or disclose her PHI for research purposes by submitting a valid authorization. Authorizations for research purposes shall contain the core elements and statements required by 45 CFR § 164.508 as articulated in WDH Policy AS-002; Client Privacy Rights. An authorization to use or disclose PHI for research purposes:
   a. Does not require a fixed expiration date or event; "end of research study," "none," or similar language suffices for such uses or disclosures.
   b. May be revoked by the individual in writing at any time. However, revocation shall not apply to the extent that WDH has taken action in reliance to the authorization prior to revocation.
   c. May be required for WDH to provide research-related treatment.

3. **Uses or disclosures without an authorization**
   a. WDH may use or disclose PHI for research purposes without a valid authorization only if:
      i. WDH obtains documentation that a waiver of individual authorization has been approved by either:
         A. An institutional review board (IRB); or

B. A privacy board that:
    I. Includes members of varying backgrounds and professional competency to review the effect of the research protocols on the individual's privacy rights;
    II. Includes at least one member who is not affiliated with WDH or the research professional and not related to any person affiliated with WDH or the research professional;
    III. Does not include any member participating in a review of any project in which the member has a conflict of interest; and
ii. WDH negotiates a written confidentiality agreement prior to disclosing PHI to an external research professional.

b. Documentation of waiver of authorization approval shall include:
    i. A statement identifying the IRB or privacy board and the date on which the waiver of authorization was approved.
    ii. A statement that waiver criteria have been met, including the following:
        A. Use or disclosure of PHI involves no more than a minimal risk to the individual based on:
            I. An adequate plan to protect individual identifiers from improper use or disclosure;
            II. An adequate plan to destroy individual identifiers; and
            III. Adequate assurances that the PHI will not be reused or disclosed;
        B. The research could not practicably be conducted without the waiver; and
        C. The research could not practicably be conducted without the PHI.
    iii. A brief description of the PHI the IRB or privacy board has deemed necessary.
    iv. A statement indicating whether the waiver of authorization has been reviewed and approved under normal or expedited review procedures as described in 45 CFR § 164.512(i)(2)(iv)(A)-(C).
    v. Signature by the chair or chair designee of the IRB or privacy board.

c. The written confidentiality agreement shall:
    i. Establish specific safeguards for the PHI;
    ii. Ensure the research professional will only report or publish findings in a manner that does not identify the individual (pictures or visual representations are expressly prohibited from use in such reports or findings);
    iii. Require the research professional to destroy individual identifiers as soon as the purposes of the research project have been accomplished, and to report such destruction to WDH in writing;
    iv. Prohibit subsequent disclosure of the PHI except as required by law or authorized by the individual; and
    v. Require the signatures of the research professional, any of the research professional's team members who require access to the PHI, and of the WDH Director.

d. A data use agreement or business associate agreement suffices for the written confidentiality agreement provided such DUA or BAA includes all elements required for the written confidentiality agreement.

e. WDH may reasonably rely on a research professional's documentation of IRB or privacy board waiver of authorization that the PHI requested is the minimum necessary for the research purpose.

4. **Retention.** WDH shall document all disclosures of PHI for research purposes and retain such documentation for six (6) years from the date of its creation or the date it was last in effect, whichever is later.

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Forms:

Policies:
AS-002; Client Privacy Rights
AS-003; Uses and Disclosures of Protected Health Information
AS-004; Minimum Necessary Information
AS-007; De-Identification and Re-Identification of Protected Health Information; Limited Data Sets and Data Use Agreements
AS-012; Designated Record Sets

References:
45 CFR § 164.501
45 CFR § 164.508
45 CFR § 164.512(i)
45 CFR § 164.514
45 CFR §§ 164.528-532
Wyo. Stat. Ann. §§ 9-2-125 and 9-2-126

Training: